**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF MISSOURI**
**CENTRAL DIVISION**

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| Michael G. Postawko, *et al.*, | ) | |
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| Plaintiffs, | ) | |
| | ) | |
| v. | ) | No. 2:16-CV-04219 NKL |
| | ) | |
| Missouri Department of Corrections, *et al.*, | ) | |
| | ) | |
| Defendants. | ) | |
| | ) | |

**DECLARATION OF DR. BLAIR THEDINGER**

1. I am over the age of 18. I have personal knowledge of the facts set forth in this declaration and could testify competently to those facts.

2. My name is Dr. Blair Thedinger, M.D. I am a physician licensed to practice medicine in the state of Missouri. I am employed by the KC CARE Clinic, a federally qualified health center in Kansas City, Missouri. I am board certified in Family Medicine and I have been credentialed as an HIV Specialist through the American Academy of HIV Medicine. I have treated hundreds of patients with Hepatitis C since 2013 at the KC CARE Clinic. I regularly consult with colleagues on advances in Hepatitis C treatment and attend Hepatitis C-focused medical conferences. I am a primary investigator on clinical trials investigating new Hepatitis C treatments.

3. The current prevailing medical standard of care for persons infected with Hepatitis C Virus (HCV) was developed by the Infectious Diseases Society of America (IDSA) and the American Association for the Study of Liver Disease (AASLD). Their evidence-based, expert-developed guidelines for Hepatitis C management are made clearly

**Exhibit 5**

available for all medical providers through their regularly updated website http://www.hcvguidelines.org.

4. The CDC encourages health care professionals to follow the AALSD/IDSA standards of care, which are evidence based, and to consult the above website.

5. When the evidence-based IDSA/AASLD standard of care was updated immediately after the first DAA drug was approved, these organizations provided "prioritization tables" and guidance on selecting patients with the greatest need because the "infrastructure . . . did not yet exist to treat all patients immediately."

6. On July 6, 2016, IDSA and AASLD updated the standard of care in recognition of the fact that continuing medical research has demonstrated the safety, tolerability, and dramatic benefits of treating *all* persons with chronic HCV.

7. Under the current prevailing medical standard of care, treatment with a DAA drug should be considered for every person with a chronic HCV infection, except those with a very limited life expectancy that cannot be remediated by treatment of Hepatitis C or liver transplantation.

8. Under the current prevailing medical standard of care, treatment with DAA drugs is expected to benefit nearly all chronically infected persons and the AASLD and ISDA recommend treatment for all patients with chronic HCV infection. The benefits of treatment and cure of Hepatitis C have been made absolutely clear by an abundance of medical evidence. The benefits to cure are accrued at early stages of the disease when there is minimal or no detectable liver fibrosis and at late stages of the disease, when a patient has developed cirrhosis. Analysis of liver biopsy results from randomized controlled clinical trials of Hepatitis C treatment has shown that people who were cured

of Hepatitis C experienced significant improvement in liver fibrosis. (Poynard, 2002b) **Cure of Hepatitis C is associated with a 70% reduction in the risk of liver cancer and a 90% reduction in the risk of liver-related mortality and liver transplantation compared to patients who are not cured by treatment or who are not offered treatment.** (Morgan, 2013); (van der Meer, 2012); (Veldt, 2007).

9. Patients cured of Hepatitis C consistently report improvements in their quality of life in medical studies, including improvements in rates of fatigue, joint pains, and social and emotional health. (Boscarino, 2015); (Neary, 1999); (Younossi, 2013).

10. The benefits of treatment at earlier stages of liver fibrosis are clear. **Long-term follow up studies of patients treated and cured of Hepatitis C at an earlier fibrosis stage demonstrate statistically significant improvement in overall survival rates for patients who were cured when compared to patients who were not cured or were not offered treatment.** (Jezequel, 2015). Furthermore, modeling studies have demonstrated that delaying Hepatitis C treatment until patients have developed more advanced liver fibrosis resulted in a 2-5 times higher rate of liver-related mortality among the patients compared to those offered treatment at an earlier stage. (Zahnd, 2015).

11. Delaying treatment for patient with chronic Hepatitis C because they have early stage fibrosis is not supported by current medical evidence. Denying treatment to a patient due to a low APRI score (or any other measurement of liver fibrosis that predicts early stages of liver damage) is a violation of the current medical standard of care for persons with HCV.

12. It is not medically necessary, or appropriate, to require an affirmation that a person will abstain from intravenous drug use or other risky behaviors before providing treatment

with DAA medication to an HCV-positive person. **Studies of HCV treatment in persons who inject drugs have shown that adherence and treatment efficacy rates are comparable to those patients who do not use injection drugs.** (Aspinall, 2013).

13. It is not medically necessary, or appropriate, to require that a patient with HCV be experiencing certain symptoms before providing treatment with DAA medications. Patients can and do have progression of liver disease while asymptomatic.

14. It is not medically necessary, or appropriate, to require a life expectancy of >18 months before providing treatment with a DAA drug to an HCV-positive person. If a patient has a life expectancy that can be confidently estimated to be less than 12 months and treatment of Hepatitis C or other directed treatment cannot alter that prognosis, it would be reasonable to defer treatment and focus on palliative care.

15. HCV is highly communicable, especially in correctional settings. Individuals who have been cured of Hepatitis C can no longer transmit the virus to others. There is a clear public health benefit to widespread treatment of Hepatitis C. Models have shown that even modest increases in the rates of successful treatment of HCV infection among persons who inject drugs can decrease the prevalence and incidence of this disease. (Martin, 2013); (Durier, 2012); (Martin, 2013); (Hellard, 2012).

16. Patients without a history of serious mental health conditions should not be required to undergo any evaluation by a mental health professional prior to Hepatitis C treatment. Modern Hepatitis C treatment that does not include Interferon does not pose significant risk of depression or other mental health conditions. In the majority of clinical trials evaluating the safety and efficacy of newer DAA Hepatitis C treatments, rates of mental

health-related adverse events did not differ significantly between placebo and the DAA under study.

17. Denying treatment or delaying treatment for a patient with Hepatitis C due to a mental health condition such as depression or anxiety is not medically justifiable. All available evidence suggests that treatment and cure of Hepatitis C is more likely to lead to improvement in a mental health condition than worsen it.

18. Delaying HCV treatment for nonmedical reasons is inappropriate and exposes an HCV-positive person to progression of liver fibrosis and a substantial risk of complications.

19. A substantial risk of complications from HCV is inherent in the condition. That is, complications can occur at any time, even immediately after a person is infected. Complications can include, but are not limited to: Hepatitis C-associated cryoglobulinemia (a serious disease state where abnormal protein clumps can form in the blood and block circulation), renal disease which can be severe and result in renal failure, increased risk of liver cancer, increased risk of diabetes mellitus, and neurologic disease. Treatment of HCV can reduce the risk of these complications (Conjeevaram, 2011); (Hsu, 2015), (Torres, 2015), which are not linked to fibrosis stage (Allison, 2015); (Petta, 2016).

20. It is not accurate to say that a substantial portion of patients with Hepatitis C will not experience complications. All patients with Hepatitis C face substantial risk of progression of liver fibrosis, non-liver related complications such as those mentioned above, and impacts on quality of life from common symptoms such as fatigue and joint pains.

21. Delaying treatment after a diagnosis of acute Hepatitis C infection is reasonable. Acute Hepatitis C is usually defined as either a patient with a negative Hepatitis C antibody test who has a positive HCV viral load or a positive HCV antibody test after a previous negative with a known recent discrete exposure event. In the setting of acute Hepatitis C, it is current standard practice to monitor the HCV viral load regularly for evidence of spontaneous resolution for 6 months to 12 months. If the patient does not experience spontaneous resolution, treatment of now chronic Hepatitis C with current standard of care medication would be recommended.

22. The newer DAA medications are appropriate for the overwhelming majority of Hepatitis C-infected patients. Patients with a true allergic reaction to these agents are exceedingly rare and I have never witnessed one in my clinical practice. Some patients are on medications that can interact with these agents but simple adjustment to medications can be made by a qualified provider in almost all cases in order to safely treat the Hepatitis C.

23. Undue delays and denials of treatment are not medically justifiable and will result in harm to persons infected with Hepatitis C.

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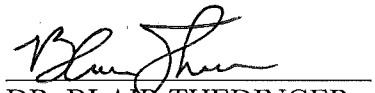
Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.



DR. BLAIR THEDINGER

3/23/17

DATE